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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,072	09/19/2003	Olivier Courtin	146.1341-DIV.	7666
47888	7590	02/01/2006	EXAMINER	
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 02/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/666,072

Applicant(s)

COURTIN ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-38, 40-43, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-38, 40-43, 50, 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Pursuant to the directives of the response filed 11/25/05, claims 34-38, 41, 43 have been amended, claim 39 cancelled, and claims 50-51 added. Claims 34-38, 40-43, 50, 51 are now pending.

Applicants' arguments filed 11/25/05 have been considered and found persuasive in part. The "ODP" rejection of claim 43 is withdrawn, in view of the terminal disclaimer. The rejection of claim 37 under 35 U.S.C. §101 is withdrawn. The rejection of claims 34-43 under 35 U.S.C. §112, first paragraph (enablement) is withdrawn.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 51 recites the phrase "pharmaceutical preparation in the form of a solution". There does not appear to be descriptive support for this. It is noted that the term "solution" occurs in 18 locations in the application, but in each

case is referring to chemical reactions, not pharmaceutical formulations.

Using the patent (USP 6,677,429) as a reference point, it is noted that there is descriptive support (col 6, line1) for “injectable preparations”, and (col 6, line 14) for a composition dissolved in water. One could perhaps make the argument that if the pharmaceutical composition in question is an “injectable preparation”, there is implied support for that particular preparation being a solution. But if the composition is a pharmaceutical composition, and at the same time is not an “injectable preparation”, descriptive support for that pharmaceutical composition being a solution would be lacking. Similar to the foregoing, claim 41 recites the phrase “said solution is obtained by dissolving a powder ... in an appropriate medium”. While noting that descriptive support exists for claim 42, the same cannot be said for claim 41.

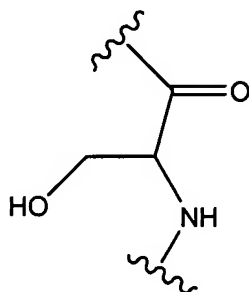


Claims 34-38, 40-43, 50, 51 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 38 recites that the compound in question is administered not as such, but rather as a composition. Accordingly, claim 38 is not properly dependent on claim 34 or on claim 43, since both of these claims (34 and 43) are drawn to a compound or to a method of using a compound.
- Claim 41 recites the phrase “said solution”. As it happens, this phrase lacks antecedent basis. It is noted that claim 51 recites the phrase “pharmaceutical preparation in the form of a solution”. However, the phrase “in the form of a solution” is an adjective phrase modifying

“pharmaceutical preparation”, whereas claim 41 implies that the “solution” is a noun, and that the solution is being used as such.

- Claim 50 is drawn to a composition that comprises a compound. The term “composition” mandates that at least one other compound be present, or else that a carrier must be present. The claim is thus indefinite as to the nature or identity of that second compound or component. The same defect afflicts claim 51.
- In claim 43, “Z” can correspond to just one substituent group. Accordingly, “Z” should be eliminated from the claim. The same applies to variable R<sub>4</sub>.
- In the compound of claim 43, a serine is present. The side chain is, of course, -CH<sub>2</sub>OH. However, the hydrogen atom shown is superfluous, and should be eliminated, i.e., the following can be used:



- In claim 43, variables R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> are recited, wherein the number (2, 3 or 4) appears as a subscript. In the definition of the variables, none of variables R<sub>2</sub>, R<sub>3</sub> and R<sub>4</sub> is defined. Instead, variables R<sub>2</sub>, R<sub>3</sub> and R<sub>3</sub> have been defined. Consistency should be maintained.
- In claim 43, the phrase “or a pharmaceutically acceptable acid addition salt” should be preceded by a semicolon.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800